

Implementing an intervention to improve adverse incident reporting in the hospital setting: A pilot study

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Research note

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Abstract

Objective: This pilot study evaluated an intervention designed to increase error reporting among physicians. Research was conducted at University Hospital A, where data were collected from April 2017 to March 2019. The intervention began in April 2018 and consisted of the four following steps: define reporting standards, improve the incident reporting system, have the hospital administrators set clear goals and begin a visualized feedback process, and achieve support and appropriate feedback from the hospital administrator.

Results: Physicians' reporting rates were higher in FY 2018 than 2017. Particularly, differences began to occur in November of FY 2018 ($p < 0.05$, analysed using Fisher's exact test). Further, the number of reports submitted by non-physicians increased by 900 in FY 2018 compared to those in FY 2017. Based on these results, the intervention effectively increased incident reporting rates among not only physicians, but also other staff members. In this regard, reporting barriers were broken when hospital administrators encouraged employees to submit incident reports.

Introduction

Fatal accidents resulting from medical errors range from $< 5\%$ to $> 30\%$ [1], with estimates from developed nations suggesting that between 7.5% and 10.4% of patients in the acute care setting experience adverse drug events [2]. A pilot study revealed 11.3% of hospitalized cases experienced adverse events in Japan [3]. Using eight years of medical death-rate data from the United States, patient safety experts at Johns Hopkins calculated that more than 250,000 deaths per year were due to medical errors [1]. The number of patient deaths caused by adverse events annually was estimated to be between 1,326 and 1,433 in Japan [4]. To improve patient safety, it is needed to collect information related to adverse events and near-miss reports. This practice constitutes one of the strategies hospital managers use to understand the kinds of errors that occur at their hospitals.

Previous studies have focused on reporting barriers. Kaldjian et al. surveyed physicians to improve knowledge about error reporting [5]. Only about 55% of respondents knew how to report errors and only 40% knew which errors to report; hence, they recommended that institutions teach physicians ways to report errors and which errors to report. Poorolajal et al. reported that the main reasons mentioned for underreporting were: lack of effective medical error reporting systems, proper reporting forms, peer support for a person who has committed an error, and personal attention for the importance of medical errors [6]. The attitude of administration is also related to barriers to incident reporting [7]. Evans et al. reported that the most frequently stated barrier to reporting for doctors and nurses was lack of feedback [8].

The current pilot study evaluated an intervention to increase incident reporting rates. The intervention was conducted in collaboration with hospital administrators to remove barriers to reporting incidents.

Methods

Study setting

This study was conducted at University Hospital A in northern Japan from fiscal year (FY) 2017 to FY 2018. The hospital contained approximately 1,160 beds and 2,650 staff members including 530 physicians (some of whom were dentists), 1,260 nurses, and 80 pharmacists. The hospital used an electronic reporting system that required all staff members to report all types of errors and near misses. As such, this study defined the scope of incident reports to include these. The reporting system operated through a local broadband network from within the hospital, with all reports reviewed by a medical safety management department (MSMD).

Intervention methods

Randomised control trials are likely to be challenging to conduct in this area, because finding sufficient units to randomise and suitable control groups will be challenging [9]. This pilot study used a time-series design with comparisons before and after the intervention. The intervention examined in this pilot study consisted of four steps, the first of which was implemented in April 2018.

Step 1: Define reporting standards beginning in April 2018

The patient safety manual used at University Hospital A required staff to report all incidents resulting from negligence, error, or failure. However, there was no standard requiring them to submit incident reports related to sentinel events. We, therefore, collaborated with MSMD members to define reporting standards for 33 topics and identified references related to adverse events [3], used Clavien-Dindo classification for complications [10], and investigated the reporting standards of several hospitals on their homepages. As shown in Table 1, these were distributed across three categories Part 1 was related to surgery; Part 2 was related to medical events other than surgery; and Part 3 included all other events. These reporting standards were then described in the manual and announced during a patient safety meeting attended by approximately 120 risk managers, who were then required to work as departmental educators. Monthly meetings were held with these risk managers to report on their experiences in that regard.

Table 1. Defining reporting standards

Part 1: Related to surgery

1. Misidentification of patient, treatment site, method, or usage
2. Items remaining in the body, such as gauze or needles
3. Over-bleeding without predictions associated with surgery
4. Infarction, rupture, or perforation associated with invasive procedures
5. Serious complications associated with surgery
6. Nerve palsy that developed after surgery
7. Blood clot after surgery
8. Cardiopulmonary arrest or mortality during surgery
9. Anaesthesia accident involving intubation and/or extubation
10. Side effect associated with anaesthesia
11. Damage associated with Equipment malfunction and corruption
12. Emergency surgery
13. Reoperation associated with complications
14. Reoperation during admission or within seven days after discharge
15. Mortality within 30 days after surgery

Part 2: Medical events other than surgery (treatment, exam, etc.)

1. Mortality, cardiopulmonary arrest, or respiratory arrest without prediction
2. Over-bleeding without prediction
3. Shock associated with contrast medium, medication, transfusion, or blood product
4. Damage or damage possibility to patient associated with misdiagnosis, overlooked, or delayed treatment
5. Severe damage associated with overlooked exam results
6. Unexpected prolonged hypoxemia/hypoxia in full-term newborn infants

7. Brain damage or broken bones associated with falling in hospitals
8. Shock or respiratory arrest associated with aspiration or supply allergic food
9. Severe burn associated with treatment
10. Severe side effect or complication associated with treatment, exam, or rehabilitation
11. Severe damage from pressure ulcer or vascular leakage

Part 3: Other

1. Suicide or suicide attempt with inpatient
2. Severe complication during inpatient (brain infarction, heart attack, pulmonary thrombus, or cerebrovascular disease)
3. Violence from patient
4. Disappearance during inpatient
5. Stolen or lost patient baggage
6. Suffocation or other events related to bringing dangerous goods inside hospitals
7. Accidental burning or explosion

Step 2: Improvements to create a sufficient incident reporting system since September 2018

University Hospital A was using its own electronic reporting system. However, clinical staff members asked the MSMD to improve this system because reporting forms were considered too long. We therefore analysed retrospective data and altered the question format from text input to select input, offered optional inputs rather than required inputs, and removed questions that were considered less important, reducing the total questions from 78 to 35. These efforts were designed to alleviate the burdens on incident reporters. These improvements reduced the time usually needed to enter one report from 20 minutes to 5–10 minutes. MSMD announced improvements and ways to use this system in the risk managers' meeting, which was also useful for re-notifying them about ways to access and use it.

Step 3: Visualized feedback implemented by the hospital administrator since October 2018

The MSMD prepared and published monthly documents concerning the submission status of incident reports from physicians inside the hospital, while the director referred to these documents when meeting with representatives of the clinical department.

Step 4: Support and appropriate feedback from the hospital administrator throughout FY2018

The deputy director (also one of the risk managers) explained the importance of incident reporting for preventing similar incidents during one of the risk-manager meetings. He specifically explained that staff members who reported incidents would not receive inappropriate feedback from their bosses consequently. This was also established as a hospital rule and listed in the patient safety manual.

Data source and analysis

The MSMD collected data from April 2017 to March 2018. In this context, the administrator of individual information deleted personal identifiers such as patient names, identification numbers, and the names of hospital staff members. Data were then given to this study's researchers. Data were varied, including reporting data (year/month/day), related personnel's occupations, impact on the patient outcomes due to the event, and type of reports (medication errors,

transfusion errors, etc.). Differences in the reporting rates before and after the intervention each month were estimated with the use of Newcombe method [11] and compared with the use of chi-square tests. Additionally, we compared the number and types of reports. All analyses were performed using SAS statistical software, version 9.4 and JMP version 12.0 (SAS Institute, Cary, NC).

Ethics approval

This study was approved by Ethics Committees at Iwate Medical University School of Medicine. We also obtained comprehensive agreements from participating hospital staff members and posted an official notice on the hospital's website. The recruitment period lasted from 30 September to 31 October 2018, during which participating hospital staff members could refuse the use of their data.

Results

Characteristics of incident reports between FY 2017 and FY 2018

Table 2 shows the characteristics of incident reports between FY 2017 and FY 2018. Incident reports of drugs were most frequently reported by staff, while those of treatment/procedure were most frequently reported by physicians. There were differences in reporter's occupation (staff, physicians) between FY 2017 and FY 2018. Among incident reports by staff, drug report rate of FY 2018 was higher than that of FY 2017.

Table 2
Characteristics of incident reports between FY 2017 and FY 2018

	By staff			By physicians		
	FY 2017	FY 2018	p-value	FY 2017	FY 2018	p-value
	n = 5875	n = 6505		n = 400	n = 600	
Kinds of incident reports a)						
Drug	1580 (26.9)	1788 (27.5)	< 0.001	35 (8.8)	80 (12.5)	0.001
Drain, tube	1227 (20.9)	1165 (17.9)		22 (5.5)	24 (3.7)	
Treatment/procedure	694 (11.8)	707 (10.9)		236 (59.0)	303 (47.3)	
Nursing care	793 (13.5)	899 (13.8)		10 (2.5)	10 (1.6)	
Examination	499 (8.5)	524 (8.1)		28 (7.0)	53 (8.3)	
Medical device, etc.	278 (4.7)	298 (4.6)		23 (5.8)	41 (6.4)	
Blood transfusion	44 (0.7)	66 (1.0)		3 (0.8)	8 (1.2)	
Others	760 (12.9)	1058 (16.3)		43 (10.8)	122 (19.0)	
Report's impact on patients b)						
Near miss	728 (12.4)	1130 (17.4)	< 0.001	16 (4.0)	106 (16.5)	< 0.001
Error	5147 (87.6)	5375 (82.6)		384 (96.0)	535 (83.5)	
a) using χ^2 test, b) Fisher's exact test						

Reports' impact on patients was also different between FY 2017 and FY 2018. Incident reports of FY 2018 were higher in near miss both from staff and physicians.

Intervention term and reporting numbers

Table 3 shows the numbers and rates of incident reports from all staff members and physicians, with side-by-side comparisons for FY 2017 and FY 2018. Before conducting the intervention (FY 2017), physicians typically submitted around 30–40 reports per month, with the fewest in December and January (24 each; Table 3). The fewest overall number of physician-submitted reports (14) occurred in April of FY 2018, which was the same month the risk managers held their first meeting to reveal the new reporting standards for distribution to staff members. After this, reporting numbers substantially increased. Next, improvements to the incident reporting system were officially released in October, which is also when the hospital director began the visualised feedback process among physicians, whose incident reporting rates increased by 10% and higher since November of FY 2018. In particular, the highest monthly number of physician-submitted reports (79) was found in December, with the total reaching 641 in FY 2018. As shown in Table 3 and Fig. 1, differences have occurred in all reporting rates since November of FY 2018. The differences in the physicians' reporting rates (FY 2018 minus FY 2017) were 6.2% (95% confidence interval (CI), 2.9 to 9.5; $P < 0.001$) in November, 6.6% (95% CI, 3.0 to 10.0; $P < 0.001$) in December, 6.0% (95% CI, 3.1 to 9.0; $P < 0.001$) in January, 4.7% (95% CI, 1.0 to 8.2; $P = 0.012$) in February, and 3.2% (95% CI, 0.1 to 6.3; $P = 0.045$) in March.

Table 3
The number and rate of incident reports by physicians

	FY 2017			FY 2018			Differences (95% CI)	p-value
	All	By staff	By physicians	All	By staff	By physicians		
	N	N (%)	N (%)	N	N (%)	N (%)		
Apr	524	487 (92.9)	37 (7.1)	346	332 (96.0)	14 (4.0)	-3.0 (-6.0 to 0.2)	0.064
May	532	494 (92.9)	38 (7.1)	507	477 (94.1)	30 (5.9)	-1.2 (-4.3 to 1.8)	0.425
Jun	588	552 (93.9)	36 (6.1)	596	545 (91.4)	51 (8.6)	2.4 (-0.6 to 5.5)	0.108
Jul	534	492 (92.1)	42 (7.9)	599	548 (91.5)	51 (8.5)	0.6 (-2.6 to 3.9)	0.691
Aug	503	469 (93.2)	34 (6.8)	616	580 (94.2)	36 (5.8)	-0.9 (-3.9 to 1.9)	0.529
Sep	497	467 (94.0)	30 (6.0)	599	552 (92.2)	47 (7.8)	1.8 (-1.3 to 4.8)	0.243
Oct	600	563 (93.8)	37 (6.2)	744	684 (91.9)	60 (8.1)	1.9 (-0.9 to 4.6)	0.181
Nov	528	498 (94.3)	30 (5.7)	604	532 (88.1)	72 (11.9)	6.2 (2.9 to 9.5)	< 0.001
Dec	410	386 (94.1)	24 (5.9)	634	555 (87.5)	79 (12.5)	6.6 (3.0 to 10.0)	< 0.001
Jan	582	558 (95.9)	24 (4.1)	612	550 (89.9)	62 (10.1)	6.0 (3.1 to 9.0)	< 0.001
Feb	483	447 (92.5)	36 (7.5)	569	500 (87.9)	69 (12.1)	4.7 (1.0 to 8.2)	0.012
Mar	494	462 (93.5)	32 (6.5)	720	650 (90.3)	70 (9.7)	3.2 (0.1 to 6.3)	0.045
Sum	6275	5875 (93.6)	400 (6.4)	7146	6505 (91.0)	641 (9.0)	2.6 (1.7 to 3.5)	< 0.001
Using chi-square test								

Discussion

Our pilot intervention was associated with an increase in the number and rate of incident reports by physicians. Comparison from FY 2017 to FY 2018 revealed that the number of incident reports by both physicians and staff increased.

Physicians tended to report far fewer minor than major incidents [12], but near-miss reports were increasingly submitted, from 16 in FY 2017 to 106 in FY 2018. Reporting standards were focused on severe cases, but they had related treatment/procedure and drug, so that not only error cases but also near-miss cases were reported. Reasons for underreporting may include lack of knowledge, which includes how to report errors, what should be reported, and what kinds of errors to report [5]. As such, reporting criteria were defined; staff members were informed about which incidents should be reported; and the MSMD could easily educate staff accordingly. Staff members were also pleased that incident reporting times were reduced. Announcement of reporting standards in our intervention brought knowledge and information about efficient reporting systems to physicians and all staff; this intervention led to the increase in the number of incident reports. However, physician submissions only increased to constitute 2.6% (95% CI, 1.7 to 3.5) more of the total in FY 2018, thus reaching 9%. The pilot intervention effectively increased the overall number of incident reports submitted by physicians but did not reach the aforementioned 10% goal. Nevertheless, physicians submitted 241 more reports in FY 2018, with all employees submitting 871. A calculation of physician reporting rates revealed an increase in the number of all incident reports as denominators and the number of physicians reported as numerators. Hence, the overall physician reporting rates seemed small.

The pilot intervention also entailed a visualised condition feedback conducted on a monthly basis. However, effective safety feedback does not solely depend on publicised incident rates, but also requires timely, visible, and repeatable corrective actions and quality improvement processes [8]. Concerning having hospital administrators provide support and feedback, previous studies have also shown that a patient safety manager can effectively reduce the fear of reporting [13]. Most physicians believed that reduction in medical errors should be a national priority, but physicians believed that fear of medical malpractice is a barrier to reporting errors, and that greater legal safeguards are necessary for the success of mandatory reporting systems [14]. Further, this study's intervention involved hospital managers, including the director and deputy director. Finally, it seemed that employees did not feel there was inappropriate feedback (including on financial and legal matters) when reporting incidents due to the direct involvement of the hospital administrator.

Conclusion

This pilot study helped remove incident reporting barriers to increase patient safety. Issues included the establishment of (1) clear reporting standards, (2) an effective medical error reporting system, (3) feedback on what actions are/were taken, and (4) peer support/appropriate feedback from hospital administrators. A before-after intervention comparison revealed that all incident reporting rates increased (i.e., from physicians and all other staff members). Hospital administrators also encouraged employees to submit incident reports, thus effectively removing reporting barriers.

Limitations

Its primary outcome was based on measuring the number of incident reports by physicians. Hence, it did not measure factors related to reporting barriers, including non-blaming, non-punitive, and non-fearful learning cultures [15, 16]. Despite these limitations, our results are meaningful. Indeed, they should facilitate hospital leadership in encouraging and rewarding employees regarding adverse-event and near-miss reporting.

Abbreviations

FY
fiscal year
MSMD
medical safety management department

Declarations

Ethics approval and consent to participate:

The MSMD collected incident reports for the hospital administration. This retrospective observational study analysed this secondary data collected by the MSMD. The study was approved by Ethics Committees at Iwate Medical University School of Medicine (Approval number: MH2018-073). The study involved only hospital staff members, and not patients, and no intervention was developed in this study. We obtained comprehensive agreements from participating hospital staff members and posted an official notice on the hospital's website. Moreover, participating hospital staff members could refuse to the use of data during the recruitment period. The UMIN Clinical Trials Registry identification number for this study is UMIN-CTR (UMIN000041087), and the data of registration 13 July 2020 (Retrospectively registered)..

Consent for publication:

Not applicable.

Availability of data and materials:

The dataset generated and analysed during the current study are not publicly available. The dataset was permitted to be used within this study by Ethics Committees at Iwate Medical University School of Medicine because the dataset had the information from the field study and clinical staff. However, the dataset is available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author's Contributions

KK and KO conceived the study and supervised this work. NA was responsible for organising and coordinating the trial. NA, RU, and FT were responsible for data analysis and interpretation, drafting the manuscript tables and figure, and revisions to the manuscript. NA wrote the main body of the manuscript. All authors approved the final version of the manuscript. All authors contributed to writing the final manuscript.

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NA is a nurse and specializes in the fields of patient safety, fundamental and administration nursing research. NA and KK work at the MSMD, and KK and KO work as hospital administrators.

Trial registration

The UMIN Clinical Trials Registry identification number for this study is UMIN-CTR (UMIN000041087), and the data of registration 13 July 2020 (Retrospectively registered).

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Figures

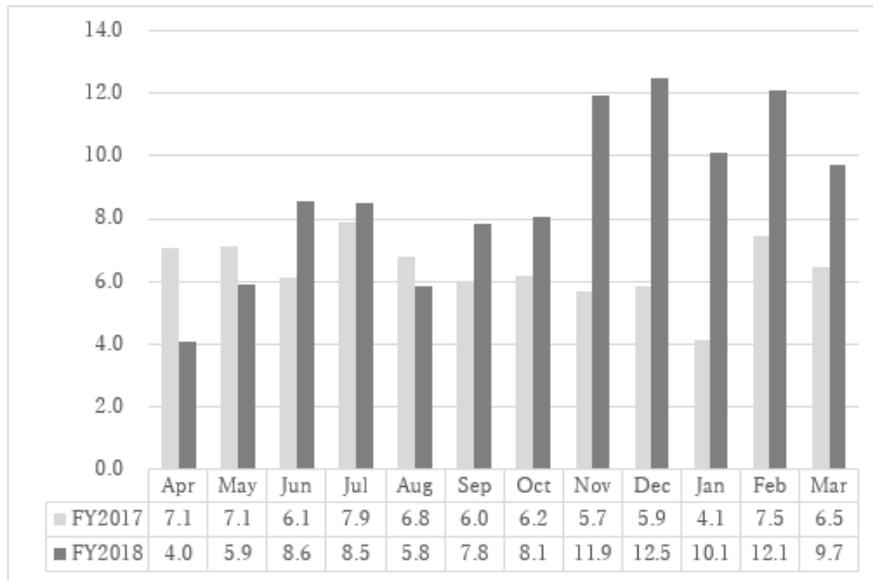


Figure 1

The rate of incident reports by physicians

Supplementary Files

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